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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,433	08/16/2001	Luc Aujame	P07180USOO/BAS	7146

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/12/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,433

Applicant(s)

AUJAME ET AL.

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-6,10 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,7,8 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1645

Election

1. Applicant's response to restriction filed on 1/14/03 paper # 12 is acknowledged. Applicant's election of Group 1 claims 1-4, 7-8 and 11-13 drawn to DNA, SEQ.ID.NO: 7 is acknowledged. Claims 1-8, 10-14 are pending in the application. Claims 5-6, 10 and 14 are withdrawn from consideration as drawn to a non-elected invention. Claims 1, 3 and 4 are withdrawn from elected invention since these claims do not recite the elected SEQ.ID.NO: 7. Therefore, claims 2, 7-8 and 11-13 with respect to SEQ.ID.NO: 7 are under examination.

Priority

2. This application is a 371 of PCT/FR 99/02643 filed on 10/28/1999. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy Application No. FRANCE 9813693 filed on 10/30/1998 has been placed in the application. The examiner has reviewed the priority documents and found that the nucleotide sequence SEQ.ID.NO: 7 containing 3204 nucleotides has been disclosed in the Application, FRANCE 9813693 and therefore, claims 2, 7-8 and 11-13 with respect to SEQ.ID.NO: 7 priority is accorded as of 10/30/1998.

Information Disclosure Statement

3. No Information Disclosure Statement has been filed with this application.

Specification - Informalities

4. It is noted that Abstract of the Disclosure is missing. If applicant desires to include the abstract from PCT/FR 99/02643, a copy of the abstract will be inserted in to the specification.

Claims should begin with "I claim" or "we claim" or "What is claimed is".

Art Unit: 1645

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The product, nucleic acid as claimed, has the same characteristics as that found in nature because the nucleic acid can be obtained from any source such as human body etc. To overcome this rejection the Examiner suggests the amendment of the claims to include the terminology such as "isolated" or "Purified". For relevant case law see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

Claim Rejections - 35 USC 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is viewed as an independent claim, drawn to an elected invention, nucleic acid which is identical or homologous to a sequence as set forth in SEQ.ID.NO: 7

Claims 12-13 are viewed as though they depend from claim 2 for examination purposes.

Art Unit: 1645

7. Claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 12-13 are viewed as though they depend from claim 2, which is drawn to "an isolated nucleic acids comprising the nucleic acid sequence as set forth in SEQ.ID.NO: 7" for examination purposes.

Instant claims are evaluated for enablement using Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

Enablement of a "pharmaceutical composition" is considered to rest on a teaching of *in vivo* administration for purposes consistent with the intended use disclosed in the specification. The nature of the invention is a pharmaceutical composition comprising a nucleic acid, SEQ.ID.NO: 7 for the treatment or prevention of pathogenic *Neisseria* strains. In addition, the instant specification does not teach how to use the claimed nucleic acid SEQ.ID.NO: 7 without undue experimentation, for the prevention, treatment, or cure of a disease in the animal to which the substance is administered. This nucleic acid may be used for inhibiting or preventing infections caused by *Neisseria* requiring *in vivo* enablement for intended use of this nucleic acid. The specification discloses that the nucleic acid of the instant invention is useful as a pharmaceutical composition for treating or preventing infections. The specification, however,

Art Unit: 1645

provides no working examples demonstrating (i.e., guidance) enablement for any *in vivo* uses of the claimed nucleic acid SEQ.ID.NO: 7. The induction of protective immune response (i.e., bactericidal and protective antibody response) to a meningococcal polypeptide or polysaccharide encoded by a nucleic acid is complex and unpredictable against all meningococcal serogroups, serotypes and serosubtypes (see abstract of *Biotechnologia Applicada* 1996, Vol 13, 1-7). It is unclear whether the claimed pharmaceutical composition, an isolated nucleic acid SEQ.ID.NO: 7 is even immunogenic i.e., antibody response. Therefore, it is unclear whether the claimed nucleic acid elicits an immune response that induces protective antibodies that are bactericidal against any serogroup. Thus, an isolated nucleic acid, SEQ.ID.NO: 7 as a pharmaceutical composition must be considered unpredictable, requiring a specific demonstration of efficacy of the claimed nucleic acid in any animal model. Absent such demonstration, the invention would require undue experimentation to practice as claimed.

Claim Rejections 35 U.S.C. 112, second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 2, 7-8 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected as being vague in the recitation "homologous" it is not clear what are the metes and bounds of homologous as written.

Claim 11 provides for the use of treatment of infection, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active,

Art Unit: 1645

positive steps delimiting how this use is actually practiced.

Claim 7 is rejected as being vague for the recitation " expression cassette-----cell." It is difficult to understand what applicant intends to mean the term "expression cassette?" Further, it is not clear what are these conditions allowing what expression in which host cell?

Claim 12 is rejected as being vague for the recitation of "naked form or in combination of at least one agent facilitating transfection". It is not clear what applicant intend to mean the term "naked?" It is difficult to understand the metes and bounds of the term "at least one agent." It is also not clear what transfection applicant is referring.

Claim 13 is rejected as being vague in reciting "vaccination vector." It is not clear what are these vaccination vectors?

Objections:

Claims 2,7-8 and 11-13 are objected, as they do not depend from the elected invention, as the claims do not recite the elected invention. I.e., an isolated nucleic acid comprising the nucleic acid sequence as set forth in SEQ.ID.NO: 7. Therefore, applicant is advised to amend claim 2 as an independent claim as it is the only claim, which recites the elected SEQ.ID.NO: 7 and amend claims 7-8, 11-13 to dependent from claim 2.

Claim Rejections - 35 USC 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2, 7-8 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammond et al U.S.Patent 5,147,800.

Art Unit: 1645

Claim 2 is viewed as an independent claim, drawn to an elected invention, nucleic acid which is identical or homologous to a sequence as set forth in SEQ.ID.NO: 7

Claims 7-8 and 12-13 are viewed as though they depend from claim 2 for examination purposes

Hammond et al disclose isolation of genomic DNA of Neisseria. Purified genomic DNA was digested with HpaII and ligated with pCP13 vector, infected into E.coli. Purified DNA read on the nucleic acid sequence homologous to sequence SEQ.ID.NO: 7 (see example 3). The purified DNA reads on nucleic acid sequence homologous to sequence SEQ.ID.NO: 7 because the limitation "homologous" is broadly interpreted. In the absence of evidence to the contrary, it is inherent that the disclosed prior art DNA comprises nucleic acid homologous to sequence, SEQ.ID.NO: 7. Since the Office does not have the facilities for examining and comparing applicants' claimed product with the product of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

It is acknowledged that weight is given to every term in claims. This is why the instant claims drawn to pharmaceutical composition are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term pharmaceutical composition must be weighed with the structural limitations of the claim. If the pharmaceutical composition merely comprises a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same nucleic acid as claimed.

Status of Claims

12. Claims 2, 7-8 and 11-13 are rejected.

Art Unit: 1645

composition merely comprises a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same nucleic acid as claimed.

Status of Claims

12. Claims 2, 7-8 and 11-13 are rejected.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886.

The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

2/5/03


**LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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